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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,337	03/13/2001	Brendan F. Murphy	DI-5585L (BXTD 9000.1)	1925
7590	02/24/2004			
Charles R. Mattenson Corp. Counsel, Renal Div. Baxter Healthcare Corp. One Baxter Parkway, DF3-3E Deerfield, IL 60015-4633			EXAMINER CHISM, BILLY D	
			ART UNIT 1654	PAPER NUMBER
DATE MAILED: 02/24/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/805,337	Applicant(s) MURPHY, BRENDAN F.	
	Examiner B. Dell Chism	Art Unit 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 3-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Withdrawal of Objections and Rejections**

The rejections and/or objections made in the prior office action filed 26 August 2003, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 26 November 2003 will be addressed to the extent that they pertain to the present grounds of rejection.

#### **Withdrawn**

##### ***Claim Rejections - 35 USC § 112***

1. Rejection of Claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn, wherein the rejection was properly traversed.
2. Rejection of Claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn, wherein the claim has structural and functional language that identifies the fragments that applicants claim as their invention.

#### **Maintained**

##### ***Claim Rejections - 35 USC § 112***

3. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The Examiner has properly applied the enablement rejection in the previous office action. Applicants made only broad sweeping statements regarding the ordinary skill of one in the art knowing simply that any sequence having 90% identity to SEQ ID NO: 2 would have the same function or be a functional equivalent. This is not a sufficient traversal of the enablement rejection. The fact that previously cited references tended to discuss identity and functionality based on new proteins does not preclude the instant claims from the fact that the function of the claimed 90% identical sequences is unpredictable and demonstrates that the Applicants were not in possession of all possible claimed inventions. Furthermore, the Applicants have not demonstrated where one of ordinary skill in the art would begin to choose which part of the sequence would be relevant to maintain the function within the 90% identity limitation. It would require undue experimentation to require one of ordinary skill in the art to select a starting point for making a functionally equivalent 90% identical sequence to SEQ ID NO: 2, because the options are limitless and the function of each possibility is not predictable as is taught in the prior art cited in the last office action. Finally, there are no working examples that offer guidance to one of ordinary skill in the art to make the invention commensurate in scope with what is claimed.

4. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the specification need only to reasonably convey clarity to those of ordinary skill in the art to demonstrate possession of the invention at the time of filing.

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Applicants state that the techniques for determining sequence identity and generating sequences with a particular % identity are well known in the art. However, applicants have not demonstrated any active binding sites or other characteristics of SEQ ID NO: 2 that would as a whole allow one of ordinary skill in the art to know or reasonably convey to one of ordinary skill in the art that all possible gaps, deletions, substitutions, etc... would maintain the same level of biological activity as that of SEQ ID NO: 2. Thus, there is no adequate description of a core sequence that must be maintained for the equivalent biological activity to remain.

Additionally, an issue arises where the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. Here, applicants argue that the specification has disclosed methods for making a 90% identical sequence to that of SEQ ID NO: 2, however, one of ordinary skill would be without any reasonably conveyed starting point that would reasonably lead that person to expect exact biological activity as that of SEQ ID NO: 2. Although one of skill in the art might get a biologically equivalent sequence within the first rounds of experimentation, it is just as likely that it would require undue amounts of experimentation to establish the desired product, i.e., a biologically equivalent sequence to that of SEQ ID NO: 2. For example, in *University Of Rochester v. G.D. Searle & Co., Inc.*, 2004 WL 260813, 11 (Fed. Cir. 2004), the courts held that, "The ' 850 patent specification also describes what can be done with any compounds that may potentially be identified through those assays, including formulation into pharmaceuticals, routes of administration, estimation of effective dosage, and suitable dosage forms. *Id.* § 5.8, at cols. 27-34. As pointed out by the district court, however, the ' 850 patent does not disclose just "**which** 'peptides, polynucleotides, and small organic molecules' have the desired characteristic

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of selectively inhibiting PGHS-2." Univ. of Rochester, 249 F.Supp.2d at 224. Without such disclosure, the claimed methods cannot be said to have been described. As we held in *Lilly*, "[a]n adequate written description of a DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." 119 F.3d at 1566\_(quoting *Fiers*, 984 F.2d at 1171). For reasons stated above, that requirement applies just as well to non-DNA (or -RNA) chemical inventions.

One of skill in the art would require a reasonably conveyed starting point in order to envisage that Applicants were in possession of all claimed inventions, and the requirement is not met.

### ***Conclusion***

5. Claim 1 is rejected and claim 2 is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

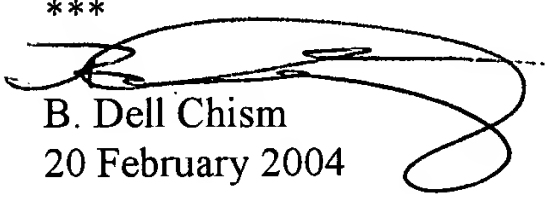
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
20 February 2004



CHRISTOPHER R. TATE  
PRIMARY EXAMINER